UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ELMER HEISNER, INDIVIDUALLY AND ON BEHALF OF, JAYNE HEISNER, Plaintiff, vs. GENZYME CORPORATION, a Massachusetts Corporation, Defendant.	Case No: 08 C 593 Judge Coar Magistrate Judge Denlow

SECOND AMENDED COMPLAINT

NOW COMES the Plaintiff, ELMER HEISNER, Individually and on behalf of the deceased, JAYNE HEISNER, ("Plaintiff"), by and through his attorneys, THE LAW GROUP, LTD., and complaining of the Defendant, GENZYME CORPORATION, states as follows:

I. PARTIES

A. PLAINTIFF

1. Plaintiff, ELMER HEISNER, is a citizen and resident of the state of Illinois.

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2. The deceased, JAYNE HEISNER, was also a citizen and resident of Illinois. JAYNE HEISNER underwent surgery to remove an ovarian cyst on January 19, 2006. At that time a Seprafilm adhesion barrier was placed into her body to prevent potential postsurgical adhesions. Plaintiff developed an intense fibrous reaction of the small intestines with collections of foreign body giant cells. Soon thereafter on February 22, 2006, JAYNE HEISNER died as a proximate result of the implanation of Seprafilm into her body. JAYNE HEISNER is survived by her husband ELMER HEISNER and her adult children: LAURA SCHMITZ, DAVID HEISNER, LINDA MCKIMMY, and CAROL HULSLANDER.

B. DEFENDANT

3. Defendant, GENZYME CORPORATION, is a Massachusetts Corporation with its principal place of business located at 500 Kendall Street, Cambridge, Massachusetts, 02142.

4. GENZYME is a life sciences company, whose core products include enzyme replacement therapy products, adhesion prevention, and other pharmaceutical products, including Seprafilm.

5. At all times relevant hereto, Defendant, GENZYME, was engaged in

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the business of designing, licensing, manufacturing, selling, marketing, distributing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, a medical device known as Seprafilm.

II. JURISDICTION

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000 exclusive of interest and costs, and because this is an action by an individual Plaintiff and Defendant who are each citizens of a different state.

7. GENZYME is a corporation headquartered in and a resident of the State of Massachusetts. Defendant has, therefore, subjected itself to personal jurisdiction and venue is proper in this District pursuant to 28 U.S.C. § 1391.

8. The Plaintiff, ELMER HEISNER, is a citizen and resident of the State of Illinois.

9. The deceased, JAYNE HEISNER, was a citizen and resident of the State of Illinois at the time of her death.

III. FACTUAL ALLEGATIONS

10. Seprafilm, manufactured by GENZYME, is intended to be a device used by medical professionals to prevent adhesions in those undergoing pelvic or laparotomy procedures by separating traumatized tissue surfaces after one undergoes pelvic and/or abdominal surgery. Adhesions are a dangerous condition

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that if left untreated can cause serious health risks, including death, to patients post surgical procedure.

11. An adhesion is an internal scar that may form after surgery on or between manipulated internal organs and/or body tissue. Adhesions between tissue can twist and pull organs out of their normal places.

12. Seprafilm Adhesion Barrier premarket approval application (PMA) was approved by the Center for Devices and Radiological Health (CDRH) of the United States Food and Drug Administration ("FDA") on August 12, 1996.

13. According to 21 U.S.C. § 360(I); Manufacturers, such as Genzyme, are required to inform the FDA of any new clinical studies or of incidents of death or serious injury related to medical devices that may have received premarketing approval (PMA).

14. The PMA applicant must submit a written report to the PMA Document Mail Center, Center for Devices and Radiological Health, Food and Drug Administration after the applicant receives or has knowledge of information concerning any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and has not been addressed by the device's labeling. [See Seprafilm PMA P950034 citing 21 C.F.R. § 814.82(a)(9)].

15. Seprafilm is composed of chemically modified hyaluronic acid and carboxymethylcellulose.

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16. Hyaluronic Acid is synthesized by humans as well as all mammalian life forms such as avian species (birds). Commercial source of hyaluronic acid can be obtained from cocks combs, chicken cartilage or microbial fermentation.

17. Individuals who have an allergy to the source animal or microorganism that synthesized the hyaluronic acid, such as birds, may have an increased risk of side effects and the potential to develop an allergic response.

IV. CLAIMS FOR RELIEF

COUNT I
STRICT LIABILITY PURSUANT TO §402A OF THE RESTATEMENT (SECOND) OF TORTS

18. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

19. The Defendant, from its headquarters in Massachusetts, made every and all decisions regarding the manufacturing, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning, post-market reporting, and otherwise distributing Seprafilm in the United States, which it sold and distributed throughout the United States to the doctors which implanted the device into the Decedent's body.

20. JAYNE HEISNER was using Seprafilm in a manner for which it was intended or in a reasonably foreseeable manner.

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21. Seprafilm was expected to and did reach the Plaintiff without substantial change in its condition as manufactured, created, designed, tested, labeled, sterilized, packaged, supplied, marketed, sold, advertised, warned, and otherwise distributed.

22. The Plaintiff was not aware of, and reasonably could not have discovered, the dangerous nature of Seprafilm's post-market approval unpublished data from clinical investigations concerning the potential for hyaluronic acid allergic reactions.

23. Subsequent to the pre-market approval of Seprafilm, the Defendant's failure to report to the FDA adverse events caused by Seprafilm as well as laboratory studies and clinical investigations which should have been known to JAYNE HEISNER concerning the potential for hyaluronic acid allergic reactions constituted a product unreasonably dangerous for normal use and ultimately caused Plaintiff to suffer from concrete intestines, an inflammatory reaction within the small bowel, significant edema and severe adherence between the small bowel loops.

24. As a direct and proximate result of GENZYME's failure to post-market report adverse events, JAYNE HEISNER suffered concrete intestines and died and consequently suffered compensatory and punitive damages in an amount to be proven at trial.

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25. GENZYME, therefore, is strictly liable to the Plaintiff. Additionally, Defendant's conduct was so outrageous as to constitute ill will, bad motive and reckless indifference to the interests of the consumers. The Plaintiff, therefore, is entitled to punitive damages.

COUNT II
NEGLIGENCE

26. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

27. It was the duty of the Defendant to use reasonable care in the design, manufacture, marketing, selling, advertising, warning, labeling, distributing Seprafilm and reporting adverse events and unpublished reports from any clinical investigation to the FDA.

28. Contrary to its duty, the Defendant was guilty of one or more of the following careless and negligent acts and/or omissions:

(A). Failed to adequately and properly test and inspect Seprafilm so as to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured and sold;

(B). Failed to utilize and/or implement a reasonably safe design in the manufacture of Seprafilm;

(C). Failed to manufacture Seprafilm in a reasonably safe condition for which it was intended;

(D). Failed to adequately and properly warn Plaintiff and Plaintiff's health care provider purchasing Seprafilm of the risks of

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complications when used in a manner for which it was intended;

(E). Failed to adequately and properly warn Plaintiff and/or Plaintiff's health care provider purchasing Seprafilm of the risks of diseases, specifically of the risk of a known allergy to hyaluronic acid, when used in a manner for which it was intended;

(F). Failed to adequately and properly label Seprafilm so as to warn the Plaintiff of the risks of complications from a known allergy to hyaluronic acid;

(G). Failed to adequately and properly label Seprafilm so as to warn the Plaintiff of the risks of concrete intestines and a known allergy to hyaluronic acid;

(H). Manufactured Seprafilm which constituted a hazard to health;

(I). Manufactured Seprafilm which caused adverse side effects; and

(J). Failed to adequately and properly report post-market adverse events and warn of potential hyaluronic acid allergic reaction.

(K) Were otherwise careless and negligent.

29. As a direct and proximate result of GENZYME's marketing, selling, advertising, labeling, distributing Seprafilm and failing to report adverse events and unpublished clinical investigations to Plaintiff, Plaintiff is at an increased risk of developing concrete intestines and has suffered compensatory and punitive damages in an amount to be proven at trial.

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COUNT III
NEGLIGENCE PER SE

30. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

31. GENZYME had an obligation not to violate the Premarket Approval Regulations pursuant to the Medical Device Amendments codified at 21 U.S.C. § 360, et seq.; §360(e)(1)(A-D); 21 C.F.R. 801.1; 801.6; 801.109; 803.50; 21 C.F.R § 814.39(d)(1) and (2); 21 C.F.R. §814.84(b)(1) and 814.84(b)(2)(i-ii) and the specific August 12, 1996 Seprafilm Premarket Approval (PMA) Order Number P950034 and Supplement Number 027, in the manufacture, design, formulation, compounding, testing, production, processing, assembly, inspection, research, distribution, marketing, labeling, packaging, preparation for use, sale, warning of the risks and dangers of Seprafilm, post- approval changes made to the device, post-market reporting of death or serious injury and unpublished clinical investigations to the FDA.

32. Plaintiff, as a purchaser and consumer of Seprafilm, is within the class of persons the statutes and regulations described above are designed to protect and Plaintiff's injury is of the type of harm these statutes are designed to prevent.

33. GENZYME's acts constitute an adulteration and/or misbranding and violation of the Medical Device Amendments codified at 21 U.S.C. § 360. et seq. and the specific Seprafilm PMA P950034 and post-approval reporting

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requirement of adverse reactions and sensitivity reactions codified at 21 C.F.R. § 814.84(b)(1); 814.84(b)(2)(i-ii); 803.50; 814.82(a)(9), therefore constitutes a breach of duty subjecting GENZYME to civil liability for all damages arising therefrom, under theories of negligence per se.

34. GENZYME failed to meet the standard of care set by the following statutes and regulations, which were intended for the benefit of individuals such as the Plaintiff, making GENZYME negligent per se:

(A) The labeling lacked adequate information on the use of the product Seprafilm [21 C.F.R. Section 801.1; 801.5;

(B) The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitations, concrete intestines and other adverse medical conditions as soon as there was reasonable evidence of their association with the product [21 C.F.R. 801.4; 801.5; 801.109; Seprafilm PMA P950034 Supplement Number 027

(C) There was inadequate information for patients and/or health care providers for the safe and effective use of GENZYME's product [21 C.F.R. 801.5; 801.109];

(D) There was inadequate information regarding special care to be exercised by the doctor for safe and effective use of GENZYME's product [21 C.F.R. 801.5; 801.109]; and

(E) The labeling was misleading and promotional [21 C.F.R. 801.6].

(F) Genzyme failed to adequately and properly report adverse events or sensitivity reactions attributable to the device, specifically the death of Plaintiff, that was reported voluntarily to the FDA by Plaintiff's family on June 5, 2006

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[21 C.F.R. § 803.50; 814.82(a)(9); FDA Manufacturer and User Facility Device Experience Database (MAUDE), Adverse Event Report Number MW1039481found at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.cfm?MDRFOI__ID=726082, Seprafilm PMA P950034]

(G) Genzyme excluded clinical trial participants exhibiting known allergies to hyaluronic acid in the in the November 29, 2007 post-market Cesarean Delivery study conducted by Winthrop-University Hospital, NCT00565643, but has still failed to report to the FDA and make appropriate post-market label changes to their Warning Section of their package insert to reflect this warning [21 C.F.R. 814.84(b)(2)(i-ii); 803.50; 814.82(a)(9)(2); See Plaintiff's Autopsy Report from BroMenn Healthcare; Seprafilm PMA P950034; See http://www.clinicaltrials.gov/ct2/show/NCT00565643?term=NCT00565643&rank=1].

[H} Genzyme failed to report to the FDA adverse reactions and or sensitivity reactions to Hyaluronic Acid that have not been addressed by the device's label, according to the Seprafilm PMA regulations 21 C.F.R. 814.82(a)(9) and 803.50, which

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attributed to Plaintiff's death [21 C.F.R. § 814.82(a)(9) and § 803.50; Seprafilm PMA P950034].

35. As a result of Plaintiff's failure to comply with the FDA's post-marketing reporting requirements codified at 21U.S.C. § 360i; 21 C.F.R. 814.84(b)(1); 814.84(b)(2)(i-ii); 803.50, Plaintiff suffered injuries, specifically, but not limited to marked intra-abdominal fibrous adhesions with foci of foreign body giant cells and an intense inflammatory reaction involving the small bowel resulting in death and damages as alleged herein.

COUNT IV
BREACH OF EXPRESS WARRANTY

36. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

37. GENZYME expressly warranted to Plaintiff, by and through statements made by GENZYME or their authorized agents, orally and in publications, package inserts, Seprafilm PMA P950034 and other written materials intended for physicians, medical patients and the general public, that Seprafilm was safe, effective, fit and proper for its intended use.

38. Specifically, Genzyme expressly warranted that "Seprafilm Adhesion Barrier can be expected to reduce adhesions within the abdominopelvic cavity. Approximately 24 to 48 hours after placement, the membrane becomes a hydrated gel that is slowly resorbed within one week. Components are excreted in less than 28 days." [Seprafilm Package Insert, found at:

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http://www.seprafilm.com/pdf/seprafilm_package_insert.pdf; Seprafilm PMA P950034]

39. Genzyme also expressly warranted that Seprafilm Adhesion Barrier is "indicated for use in patients undergoing abdominal or pelvic laparotomy as an adjunct intended to reduce the incidence, extent, and severity of postoperative adhesions between the abdominal wall and the underlying viscera such as omentum, small bowel, bladder, and stomach, and between the uterus and surrounding structures such as tubes and ovaries, large bowel, and bladder."[Seprafilm Package Insert, found at: http://www.seprafilm.com/pdf/seprafilm_package_insert.pdf; Seprafilm PMA P950034]

40. Genzyme further warranted in its PMA Protocol HF91-1202 "Evaluation of the Safety of Seprafilm Bioresorbable Membrane in Gynecologic Surgery: Patient Enrollment: April 27, 1992-July 12, 1993" the following:

[A] That no serious adverse events were reported in this study {Seprafilm PMA Order P950034 Attachment Tab B, pg. 13].

[B] No known contraindications or precautions were identified in this study {Seprafilm PMA Order P950034 Attachment Tab B, pg. 13].

[C] It was concluded that the application of Seprafilm to the uterus in gynecologic surgery resulted in no clinically significant changes in vital signs or laboratory values that

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> altered any patient's expected course of surgical recovery or resulted in the occurrence of serious adverse events
>
> {Seprafilm PMA Order P950034 Attachment Tab B, pg. 13].

41. In using Seprafilm, Plaintiff relied on the skill, judgment, representations and foregoing express warranties of GENZYME. Said warranties and representations were false in that the aforementioned product was not safe and was unfit for the uses for which it was intended due to the fact that Plaintiff developed adhesions of the small intestines, small bowel loops to abdominal wall with leakage of stool material and marked intra-abdominal fibrous adhesions with foci of foreign body giant cells resulting in death. [Plaintiff's Autopsy Report from BroMenn Healthcare].

42. As a direct and proximate result of GENZYME's breach of warranty, JAYNE HEISNER was at an increased risk of developing concrete intestines, an inflammatory reaction within the small bowel, significant edema and severe adherence between the small bowel loops and therefore has suffered compensatory and punitive damages in an amount to be proven at trial.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiff, ELMER HEISNER, by and through his attorneys, THE LAW GROUP, LTD., prays for relief as follows:

1. For general damages in a sum in excess of the jurisdictional minimum of this Court;
2. Medical, incidental, hospital and service expenses according to proof;
3. Loss of earnings and earning capacity according to proof;
4. Prejudgment and post judgment interest as provided by law;
5. Compensatory damages in excess of the jurisdictional minimum of the Court, according to proof;
6. Consequential damages in excess of the jurisdictional minimum of the Court, according to proof;
7. Damages for the Wrongful Death of JAYNE HEISER pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1;
8. Damages awarded pursuant to the State of Illinois Survival Act, 755 ILCS 5/27-6, 740 ILCS 180/2;
9. Damages for loss of consortium and society;
10. Punitive and exemplary damages;
11. Attorneys' fees, expenses and costs of this action; and
12. Such further relief as this Court deems necessary, just and proper.

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DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all claims so triable in this action.

RESPECTFULLY SUBMITTED,

By: /s/ Kurt D. Hyzy
Kurt D. Hyzy, #6196871
Pamela G. Sotoodeh, #6284622
Lynn M. Herbstman, #6286390
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CERTIFICATE OF SERVICE

I do hearby certify that, on this 3rd day of September, 2008, a true and correct copy of **Plaintiff, Elmer Heisner's, Individually, and on Behalf of Jayne Heisner, Second Amended Complaint** was served electronically upon the following individual:

Stephanie A. Scharf
Schoeman Updike Kaufman & Scharf
33 W. Wacker Dr., Suite 300
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By: /s/ Kurt D. Hyzy
Attorney for Plaintiff
Kurt D. Hyzy, #6196871
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